System and Method for Providing a Breathing Gas

Field of the Invention

[0001] The invention relates generally to the delivery of a breathing gas to an airway of a patient, and more particularly, to the delivery of a breathing gas coordinated with the breathing cycle of the patient.

Background

[0002] Obstructive sleep apnea is an airway breathing disorder caused by relaxation of the muscles of the upper airway to the point where the upper airway collapses or becomes obstructed by these same muscles. It is known that obstructive sleep apnea can be treated through the application of pressurized air to the nasal passages of a patient. The application of pressurized air forms a pneumatic splint in the upper airway of the patient thereby preventing the collapse or obstruction thereof.

[0003] Within the treatment of obstructive sleep apnea, there are several known CPAP regimens including, for example, mono-level CPAP and bi-level CPAP. Mono-level CPAP involves the constant application of a single therapeutic or medically prescribed CPAP level. That is, through the entire breathing cycle, a single therapeutic positive air pressure is delivered to the patient. While such a regimen is successful in treating obstructive sleep apnea, some patients experience discomfort when exhaling because of the level of positive air pressure being delivered to their airways during exhalation.

[0004] In response to this discomfort, bi-level CPAP regimens were developed. Bi-level CPAP involves delivering a higher

therapeutic CPAP during inhalation and a lower therapeutic CPAP during exhalation. The higher therapeutic CPAP level is commonly known as inspiratory positive airway pressure or "IPAP." The lower therapeutic CPAP level is commonly known as expiratory positive airway pressure or "EPAP." Since the EPAP is lower than the IPAP, the patient needs to do less work during exhalation to exhale and thus experiences less discomfort, compared to the mono-level CPAP regimen.

[0005] However, the development of bi-level CPAP significantly increased the sophistication of CPAP devices because the devices must accurately determine when the patient is inhaling and exhaling and to properly coordinate the IPAP and EPAP levels thereto. One approach is to determine the instantaneous and average flow rates of air being delivered to the patient and then to compare the two to determine whether a patient was inhaling or exhaling. If the instantaneous flow rate is greater than the average flow rate, the patient is deemed to be inhaling. If the instantaneous flow rate is less than the average flow rate, the patient is deemed to be exhaling.

[0006] While CPAP has been useful in the treatment of obstructive sleep apnea and other respiratory related illnesses such as, for example, chronic obstructive pulmonary disease and neuro-muscular disorders affecting the muscles and tissues of breathing, it is highly desirable to provide additional ways of delivering a therapeutic breathing gas to a patient.

Summary

[0007] According to one embodiment, a method of providing a breathing gas is described. The method includes, for example,

sensing a parameter associated with the delivery of a breathing gas, changing a valve position in response to a change in the sensed parameter, determining a breathing state based on the valve position, and causing a change in the sensed parameter of the breathing gas based on the determined breathing state.

Brief Description of the Drawings

[0008] In the accompanying drawings which are incorporated in and constitute a part of the specification, embodiments of the invention are illustrated, which, together with a general description of the invention given above, and the detailed description given below, serve to example the principles of this invention.

[0009] Figure 1 is one embodiment of functional block diagram illustrating a system for delivering a breathing gas.

[0010] Figure 2 is one embodiment of a flowchart illustrating the control of the system.

[0011] Figure 3 is a graph illustrating the valve step position and mask pressure over time for one embodiment of the invention.

[0012] Figure 4 is a graph illustrating the valve step position and mask pressure over time for another embodiment of the invention.

[0013] Figure 5 is a graph illustrating the valve step position and mask pressure over time for yet another embodiment of the invention.

Detailed Description of Illustrated Embodiments

[0014] Prior to discussing the various embodiments, a review of the definitions of some exemplary terms used throughout the disclosure is appropriate. Both singular and plural forms of all terms fall within each meaning:

[0015] "Logic," as used herein, includes but is not limited to hardware, firmware, software and/or combinations of each to perform a function(s) or an action(s), and/or to cause a function or action from another component. For example, based on a desired application or needs, logic may include a software controlled microprocessor, discrete logic such as an application specific integrated circuit (ASIC), or other programmed logic device. Logic may also be fully embodied as software.

[0016] "Software," as used herein, includes but is not limited to one or more computer readable and/or executable instructions that cause a computer or other electronic device to perform functions, actions, and/or behave in a desire manner. The instructions may be embodied in various forms such as routines, algorithms, modules or programs including separate applications or code from dynamically linked libraries. Software may also be implemented in various forms such as a stand-alone program, a function call, a servlet, an applet, instructions stored in a memory, part of an operating system or other type of executable instructions. It will be appreciated by one of ordinary skill in the art that the form of software is dependent on, for example, requirements of a desired application, the environment it runs on, and/or the desires of a designer/programmer or the like.

[0017] "breathing state," as used herein, includes any state or combination of states where air is drawn into the lungs and/or expelled from the lungs. For example, a first breathing state may be associated with drawing air into the lungs and a second breathing state may be associated with expelling air from the lungs. Additionally, a breathing state can have one or more sub-states. For example, the start of inhalation can be a breathing state and the end of inhalation can be another breathing state, with the range therebetween defining one or more other breathing states. Similarly, the start and end of exhalation, and the range there between, can also be defined by one or more breathing states.

[0018] The systems and methods described herein are particularly suited for assisting the respiration of spontaneously breathing patients, though they may also be applied to other respiratory regimens including, for example, acute and homecare ventilation. Referring now to Figure 1, block diagram 100 illustrating one embodiment of a system is shown. The system has a controller 102 with control logic 104, a blower 106, a variable position poppet valve 108 with a bi-directional stepper motor and a pressure sensor 112. A flow path 110 provides a path for a flow of breathable gas from the valve 108 to a patient interface 114. Patent interface 114 can be any nasal mask, face mask, cannula, or similar device. Pressure sensor 112 senses a parameter of the breathing gas such as the pressure in flow path 110, which is associated with and indicative of the pressure in the patient interface 114. The controller 102 is preferably processor-based and can various input/output circuitry including analog-to-digital (A/D) inputs and digital-to-analog (D/A) outputs. The controller 102 sends valve step position data 116 to the valve 108 to control its

position and the sensor 112 sends pressure data 118 back to the controller 102 to be read.

[0019] The valve step position is preferably defined by the stepper motor specification and can include step positions that are less than 1 step or a whole step. Generally, the valve step position can range from any negative number to any positive number. One preferable valve step position range includes 0 to 100, where step position 0 is associated with a fully closed valve position and step 100 is associated with a fully open valve position. Therefore, for a given blower speed and valve configuration, each valve step position can be determined to be equivalent to an approximate pressure change (e.g., a valve step position equals a pressure change of 0.2 cm H_2O.)

[0020] While the embodiment of Figure 1 has been described with reference to a flow/pressure control element in the form of a variable position valve 108 and a sensor element in the form of a pressure sensor 112, the flow/pressure control and sensor elements can include other types of devices. For example, the flow/pressure control element can be a variable speed blower with a linear valve or solenoid valve, alone or in combination with a stepper motor controlled variable position valve. The sensor element can include a flow sensor, temperature sensor, infra-red light emitter/sensor, motor current sensor, or motor speed sensor alone or in combination with the pressure sensor. The data generated from these sensor(s) is fed back to the controller 102 for processing.

[0021] Referring now to Figure 2, the operation of the system will be described with reference to the flowchart illustrated therein. In the flowchart, the rectangular elements denote processing blocks and represent software instructions or groups

of instructions. The quadrilateral elements denote data input/output processing blocks and represent software instructions or groups of instructions directed to the input or reading of data or the output or sending of data. The flow diagrams shown and described herein do not depict syntax of any particular programming language. Rather, the flow diagrams illustrate the functional information one skilled in the art may use to fabricate circuits or to generate software to perform the processing of the system. It should be noted that many routine program elements, such as initialization of loops and variables and the use of temporary variables are not shown.

[0022] In block 200, the controller 102 opens the valve 108 and sets the blower 106 to a speed that produces a predetermined pressure at the its output. This predetermined pressure is generally set to a medically prescribed positive pressure for a patient, plus an additional pressure of 5 cm H_2O, via a pressure-to-speed look-up table that is stored in the memory of the controller 102. While an additional pressure of 5 cm H_2O has been described, other pressures including no additional pressure can be chosen as well. The medically prescribed positive pressure is typically a pressure that is above the ambient pressure and can range anywhere from 2 to 20 cm H_2O. Once the blower 106 is set to provide the set pressure, it is rarely, if ever, changed during active operation of the device. Instead, the controller 102 uses the step position of the valve 108 to modulate the output pressure through both a closed loop and an open loop control. The closed loop control is a function of sensed pressure and the open loop control is a function of time. Together, these control loops direct the operation of the system through the breathing cycle of a patient. It should also be noted that the closed loop and open loop control can also be

based on other parameters such as, for example, instantaneous and average flow rates, temperature of the gases in the patient interface, and/or composition of the gases (e.g. CO_2) in the patient interface.

[0023] In block 202, pressure is read and stored for subsequent processing. In block 204, an average valve step position is determined and maintained or updated. In step 206, the controller 102 determines if a pressure drop has been sensed. This is preferably accomplished by comparing the presently sensed pressure with the immediately preceding sensed pressure. If the presently sensed pressure is less, then a pressure drop has occurred and the flow proceeds to block 208. In block 208, the controller 102 increments the valve step position to compensate for the pressure drop. Incrementing the valve step position has the effect of increasing the flow and pressure of the breathing gas delivered from the valve's output. The step position is change iteratively until the error or difference between the sensed pressures is minimized. During this phase of operation, the controller 102 seeks to maintain a constant pressure in the flow path 112 until patient exhalation is sensed.

[0024] In block 210, the difference between the instantaneous and average valve position is integrated over time and stored in memory. The summation of six such integrations is used to determine the start of an inhalation breathing state by determining if the summation is greater than a start of inhalation threshold (blocks 212 and 214). If the summation is greater than the threshold, the start of the inhalation breathing state has occurred and a timer begins the measurement of the inhalation breathing state in block 216. This

measurement continues until a peak valve step position has been found in block 218. The peak valve step position is determined by comparing the previous valve step position to the present valve step position and saving in memory the step position that is greater as the peak valve step position. If the peak valve step position remains unchanged for some time period (e.g., 80 ms), then the controller 102 assumes that the peak valve step position has occurred for this inhalation phase and stops the inhalation breathing state time measurement in block 220. The peak valve step position is a threshold indicative of the imminent end of the inhalation breathing state.

[0025] In block 222, the controller 102 tests to determine if a pressure increase has occurred by reading the pressure signal. If a pressure increase has occurred after a peak valve step position has been found, then the inhalation breathing state is imminently ending. Block 224 decrements the valve position to lower the flow and pressure provided so as to maintain a constant pressure in the air flow path. This is once again accomplished by an iterative process by which the error between the presently sensed pressure and the previously sensed pressure is minimized. Block 226 tests to determine if the inhalation breathing state has ended by comparing two variables, VAR_1 and VAR_2. These variables are defined as follows:

$$VAR_1 = \text{(Inst. Step Position)} - \text{(Avg. Step Position)}$$

$$VAR_2 = [\text{(Peak Step Position)} - \text{(Avg. Step Position)}] * \text{Threshold}$$

The variable "Threshold" is a percentage value such as, for example, 0.85, though other percentage values can also be chosen. If $VAR_1 \leq VAR_2$, then the inhalation breathing state has

ended and the exhalation breathing state has or is about to commence.

[0026] Block 228 decrements the valve step position according an exhalation unloading function that lowers the pressure delivered over time so that the pressure initially delivered during the exhalation breathing state is less than the pressure delivered during the inhalation breathing state. The pressure is dropped until a predetermined minimum pressure is provided, which can include ambient pressure. This lower pressure is maintained in block 230 for an exhalation time period that is generally equal to 2.5 times the measured inhalation state time period. Multiples other than 2.5 can also be selected after the expiration of this time period, the pressure signal is read in block 232 and the valve step position is incremented according to a pressure loading function. The pressure loading function reads the present pressure and returns over time the output pressure to the medically prescribed positive pressure, where the system once again looks for a start of inhalation breathing state.

[0027] In this manner, a positive pressure is provided during the inhalation phase of a breathing cycle to assist the patient in inhalation and a lower pressure is provided during the exhalation phase of a breathing cycle to allow the patient to exhalation against a lower pressure. Such a system provides a level of comfort over other types of Continuous Positive Airway Pressure delivery in that the patient is not required to exhale against the same pressure used during inhalation for any appreciable period of time.

[0028] Referring now to Figure 3, a chart illustrating a valve step position curve 300 and an output pressure curve 302

as a function of time is shown. The two curves have been overlaid to more clearly illustrate the synchronization between pressure and valve step position. The operation description will now be reviewed with reference to the curves of Figure 3.

[0029] Prior to state 0, the system is in the closed loop control and is sensing the pressure at its output via its pressure sensor. Since there is very little pressure change prior to state 0, the system is maintaining a constant valve step position, which results in a constant output pressure (preferably, the medically prescribed positive pressure). This typically occurs at the end of patient exhalation where there is very little pressure change in the system caused by the patient.

[0030] When the patient begins to inhale, a pressure drop is sensed by the pressure sensor 112. This pressure drop causes the system to further open the valve 108 in a step-wise fashion to compensate for the drop in pressure caused by patient inhalation. During such inhalation, the system attempts to maintain an output pressure substantially equivalent to the medically prescribed positive pressure. Each step position of the valve is equivalent to a known approximate pressure change (e.g., 0.2 cm H_2O). The difference between the sensed pressure and the set pressure (i.e., the medically prescribed positive pressure) generates an error value, which the system attempts to minimize by appropriately adjusting the valve step position, which appropriately adjusts the pressure delivered.

[0031] State 0 occurs when the valve step position is increased and triggers a fixed time period which leads to State 1. During this fixed time period, the difference between the instantaneous valve step position and the average valve step position is integrated over 6 time intervals. Figure 3 shows

only 3 intervals for the sake of clarity. If the summation of these 6 integrations is greater than a threshold value, then a patient inhalation is assumed and an inhalation timer is started that measures the time of inhalation.

[0032] This inhalation time measurement is terminated when a peak valve step position has been reached in State 2. The peak valve step position is determined by comparing the previous valve step position to the present valve step position and saving in memory the step position that is greater as the peak valve step position. If the peak valve step position remains unchanged for some time period (e.g., 80 ms), then the system assumes that the peak valve step position has occurred for this inhalation phase.

[0033] After State 2, the system looks for an exhalation trigger. This is accomplished by comparing two variables, both of which are based on valve step position. The equations have defined above as VAR_1 and VAR_2. If $VAR_1 \leq VAR_2$ then the trigger exists and the system moves to State 3.

[0034] In State 3, the system closes the variable position valve 108 so as to provide a lower pressure at its output. The valve 108 can be quickly and linearly closed (e.g., with a fixed slope of 3 ms/step) by reducing the valve step position to, for example, position 0 (i.e., closed). During a significant portion of exhalation, the system now provides a lower pressure than that used during inhalation. This makes it easier for the patient to exhale.

[0035] From State 3 to State 4, the system is in open-loop control and does not vary the valve step position based on pressure or any other parameter. The valve remains in its step

position during this fixed time period. As described above, the time period can be fixed to be 2.5 times the previously determined inhalation time (i.e., time from State 1 to State 2). This is the pressure unloading portion of the system operation.

[0036] At State 4, the exhalation time period expires and the system gradually applies pressure to its output until the pressure once again reaches the medically prescribed positive pressure. The system is now re-loading the pressure at its output. This is accomplished by sensing the pressure at State 4, which is caused primarily by patient exhalation, and quickly changing the valve step position to meet that pressure. Hence, this phase of exhalation starts with a pressure that is dependent on the patient exhalation pressure. From State 4 to State 5, the system gradually changes the valve step position in a linear fashion (e.g., with a fixed slope of 40 ms/step) thereby gradually opening the valve until the output pressure once again reaches the higher medically prescribed positive pressure. The system is now ready for the next patient inhalation where the process repeats.

[0037] Figure 4 illustrates an embodiment of the invention directed to exhalation trigger-based control. In this regard, the control is the similar to that explained above, except that no inhalation trigger is provided. In particular, a breath cycle time is measured as a function of the peak valve step position. The time between two peak valve step positions (State 2) is a measure of the breathing cycle time. The exhalation trigger at State 3, unloading portion from States 3 to 4, and loading portion from States 4 to 5 are the same as described above in connection with Figure 3. The unloading portion (States 3 to 4) and loading portion (States 4 to 5) are defined

to be percentages of the breath cycle time of the previous breath cycle(s). These percentages can range broadly, but are typically chosen that the unloading and loading portion together are any where from about 50% to 85% of the breath cycle time. The advantage of this embodiment is that it requires less processing by the controller 102.

[0038] Illustrated in Figure 5 is an embodiment of the present invention that uses the instantaneous and average valve step position to detect the breathing state of a patient than coordinates the pressure delivered according to the detected states. In this embodiment, the system is in closed-loop control mode where it is always sensing the pressure and adjusting its output based thereon. More specifically, as the patient breathes, an average valve step position is established by virtue of the valve step position increasing to raise the pressure delivered for inhalation and decreasing to reduce the pressure delivered for exhalation based on the pressure fed back to the controller 102. By comparing the instantaneous valve step position to the average valve step position, the breathing state of the patient can be detected. If the instantaneous valve step position is above the average valve step position, the patient is inhaling. If the instantaneous valve step position is below the average valve step position, the patient is exhaling. To reduce premature or erratic triggering, the average valve step position can be offset above its true value for inhalation detection and below its true value for exhalation detection.

[0039] In Figure 5, reference 502 indicates the instantaneous valve step position crossing the average valve step position with a positive slope. This indicates the patient is inhaling

because the valve is increasing its step position to compensate for the drop in pressure caused by the patient inhalation. Reference 504 indicates the instantaneous valve step position crossing the average valve step position with a negative slope. This indicates the patient is exhaling because the valve is decreasing its step position to compensate for the increase in pressure caused by patient exhalation. According to such detection, an IPAP level can be applied during inhalation and an EPAP level can be applied during exhalation. Reference 506 indicates the next inhalation detection.

[0040] While the present invention has been illustrated by the description of embodiments thereof, and while the embodiments have been described in considerable detail, it is not the intention of this specification to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. For example, valve step position can be changed according to non-linear function as an alternate, addition or in combination with linear functions. Alternate or additional parameters of the flow gas can be sensed including flow rates through the use of flow sensors to modulate valve step position. More specifically, the direction of flow and/or the change in flow rates (e.g., instantaneous and average) can also be used. Therefore, the invention, in its broader aspects, is not limited to the specific details, the representative apparatus, and illustrative examples shown and described. Accordingly, departures may be made from such details without departing from the spirit or scope of the applicant's general inventive concept.